January 16, 2025

Gene Hamilton and Heidi Overton, MD
HHS Transition Team
President-elect Donald J. Trump and Vice President-elect J.D. Vance

Dear Mr. Hamilton and Dr. Overton:

We, the undersigned organizations, write to request that the Trump administration immediately rescind two guidance documents related to human cells, tissues, and cellular and tissue-based products (HCT/Ps) recently released by the Food and Drug Administration (FDA). The two documents were published in the Federal Register on January 7, 2025, and are entitled "Recommendations to Reduce the Risk of Transmission of *Mycobacterium tuberculosis* (Mtb) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)" and "Recommendations to Reduce the Risk of Transmission of Disease Agents Associated with Sepsis by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)". Both documents were issued for immediate implementation without a prior public comment period.

While we agree with the FDA that any case of Mtb or sepsis transmission through transplanted HCT/Ps is tragic, the guidance contained in the two documents will have a devastating effect on the availability of musculoskeletal and ocular tissue products and will adversely impact the availability of life transformative tissue products for patients. There are more than 2.5 million tissue transplants and grafts performed each year to restore Americans' eyesight, improve their mobility, or heal their wounds, but these guidance documents risk making otherwise safe tissue unavailable to patients in need.

We support the FDA's ability to issue guidance to improve processes and ensure the highest level of standards, but there are too many areas requiring clarification or revision to allow the effective implementation of the recommendations in the documents. Additionally, the guidance documents direct affected entities to implement the recommendations within four weeks of publication (by February 3, 2025), which is not a practical timeline. Had these documents followed the traditional FDA process and been published in draft form, allowing for public comment, our organizations could have provided feedback to ensure the recommendations were implementable on a timely basis. Unfortunately, that is not what happened. An example of some of the issues we have identified include:

- Both documents appear to require extensive consultation with the donor's "primary treating physician," raising practicality, liability, and other concerns – with an unclear benefit, as the tissue establishment medical director is best positioned to accurately assess the donor's risk for infectious disease transmission;
- The sepsis guidance requires tissue establishments to "determine to be ineligible" any donor with a risk factor for sepsis, which includes individuals "known to have a medical diagnosis of sepsis or suspicion of

sepsis." However, it is unclear as to what constitutes a "suspicion" of sepsis or who should be responsible for determining that there is a suspicion of sepsis.

- The Mtb guidance directs tissue establishments to collect information about two potential Mtb exposure risks, occupational exposure risk and current residence in a nursing home, as part of the Donor Risk Assessment Interview (DRAI) process. Adding these criteria to the DRAI is a process that would require months of planning and execution.

One key change that could have been made to both guidance documents to preserve the availability of safe tissue for transplant is to have focused solely on HCT/Ps containing viable cells that can transmit these diseases, as none of our organizations are aware of any cases of Mtb transmission through tissues that do not contain viable cells since the FDA began regulating HCT/Ps in 1993. We have shared these and other concerns with the FDA and hope the agency will rescind or pause the implementation of the two guidance documents without further direction from the Trump administration. AATB's letter to the agency can be found at https://www.aatb.org/government-advocacy-correspondences.

We also want to highlight that our organizations have already acted to support patient safety. For example, the American Association of Tissue Banks (AATB) has already published new industry requirements in the AATB *Standards for Tissue Banking,* 15th Edition, to reduce the risk of Mtb.[1,2] Similarly, the Eye Bank Association of America (EBAA) recently released guidance on screening potential donors for sepsis and Mtb, and also released updated versions of the DRAI.

The guidance documents include boilerplate language that "FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities…" and "…should be viewed only as recommendations," but in practice, we believe FDA inspectors will begin issuing citations and taking other enforcement actions against entities that do not comply with the new requirements contained in the two guidance documents. Given the potential impact to patients in need of life-transformative tissue products, and the need for our organizations to have additional time to incorporate any recommended changes from FDA into our requirements, we believe it is critical for these two documents to be rescinded and, if necessary, reissued in draft form so interested stakeholders can ask questions, provide feedback, and seek clarity on any new directives from the agency.

Thank you for taking these concerns into consideration. The 4-week implementation period ends on February 3, 2025, indicating there is still time for the new administration to rescind the guidance documents before they cause sharp declines in the number of eligible donors, reducing the supply of tissue and ocular products, and impacting patients' access to these life-transformative products. Our organizations stand ready to assist the Trump administration in whatever way that you deem appropriate.

Sincerely,

Marc Pearce, MBA
President and CEO
American Association of Tissue Banks

Dorrie Dils
President
Association of Organ Procurement Organizations

Kevin Corcoran, CAE
President and CEO
Eye Bank Association of America

[1] https://www.aatb.org/bulletin-23-6
[2] https://www.aatb.org/bulletin-24-5